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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/592,685	06/12/2000	Jeffrey Bonadio	4100.000582	4457

23720 7590 06/04/2003

WILLIAMS, MORGAN & AMERSON, P.C.  
10333 RICHMOND, SUITE 1100  
HOUSTON, TX 77042

EXAMINER

ROMEO, DAVID S

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.



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EXAMINER
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17

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**Commissioner for Patents**

See the Attached "DETAILED ACTION"

### DETAILED ACTION

The reply filed on April 7, 2003 (Paper No. 16) is not fully responsive to the prior Office Action because:

Applicant argues that the '722 application provides written description support for each  
5 of the claim terms. Specifically, Applicant argues that Section V of the preliminary amendment  
filed June 12, 2000 (Paper No. 6) cited support for the "modulating" language of claims 53 and  
54 as follows:

page 46, line 5, of the '722 application supports claims 53 and 54; and

page 58, lines 22-27, of the '722 application supports claims 53 and 54.

10 Applicant argues that Section V of the preliminary amendment filed June 12, 2000 (Paper  
No. 6) cited support for the "targeting" language of claims 55-58 as follows:

page 46, line 1, of the '722 application supports claim 55;

page 58, lines 19-22, of the '722 application supports claim 55;

page 48, lines 4-5, of the '722 application supports claim 56;

15 page 45, line 29, of the '722 application supports claim 57;

page 58, line 18, of the '722 application supports claim 57;

page 46, line 2, of the '722 application supports claim 58; and

page 58, lines 27-29, of the '722 application supports claim 58;

Applicant's arguments have been fully considered but they are not persuasive.

20 Claims 43, 45, 46, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 69, 70, 72, 74, 75, 76,  
78, 80, and 81 require providing or administering the LTBP-3 of the present invention to a  
mammal or animal or a tissue site in said mammal or animal, such that LTBP-3 binds latent

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TGF- $\beta$ , such that the binding regulates, modulates, targets, or protects latent TGF- $\beta$  in said animal or mammal. Although claim 40, as set forth in Exhibit C of the preliminary amendment filed June 12, 2000 (Paper No. 6), does support the binding of TGF- $\beta$  with LTBP-3 in a sample and identifying the TGF- $\beta$  so bound, the preliminary amendment (Paper No. 6) adds and claims  
5 additional disclosure not presented in prior Application No. 08479722, such that prior Application No. 08479722 does not support the presently claimed methods of binding TGF- $\beta$  in an animal and the modulating or targeting thereby.

Page 46, line 5, of the '722 application states "LTBP may modulate the activation of latent complexes."

10 Page 58, lines 22-27, of the '722 application states "LTBP may modulate the activation of latent complexes. This idea is based in part on recent evidence which suggests that mature TGF- $\beta$  is released from extracellular storage sites by proteases such as plasmin and thrombin and that LTBP may protect small latent complexes from proteolytic attack."

Page 46, line 1, of the '722 application states "the large latent TGF- $\beta$  complex covalently  
15 binds the extracellular matrix via LTBP-1, i.e., LTBP-1 may target the latent TGF- $\beta$  complex to a site near the cell surface (pericellular matrix) to facilitate the generation of autocrine or paracrine effects."

Page 58, lines 19-22, of the '722 application states "the large latent TGF- $\beta$  complex is covalently bound to the extracellular matrix via LTBP (Taipale et al., 1994). Based on these  
20 observations, LTBP has been referred to as a "matrix receptor", i.e. a secreted protein that targets and stores latent growth factors such as TGF- $\beta$  to the extracellular matrix."

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Page 48, lines 4-5, of the '722 application states "LTBP facilitates the assembly and secretion of latent TGF- $\beta$  complexes and targets latent TGF- $\beta$  to bone matrix."

Page 45, line 29, of the '722 application states "LTBP may function to target latent TGF- $\beta$  to specific types of connective tissue."

5 Page 58, line 18, of the '722 application states "LTBP may function to target latent TGF- $\beta$  to specific types of connective tissue."

Page 46, line 2, of the '722 application states "LTBP-1 may target the latent TGF- $\beta$  complex to a site near the cell surface."

10 Page 58, lines 27-29, of the '722 application states "LTBP may plays an important role in targeting the latent TGF- $\beta$  complex to the cell surface, allowing latent TGF- $\beta$  to be efficiently activated."

However, none of these respective pages and lines of the '722 application, disclosing the postulated in vivo biological roles of LTBP, expressly, implicitly, or inherently supports the contention that the '722 application conceived the concept of treating a mammal or animal by providing or administering the LTBP-3 of the present invention to the mammal or animal, such that the LTBP-3 binds latent TGF- $\beta$ , such that the binding modulates or targets the latent TGF- $\beta$ , as required by the present claims. The '722 application cannot describe what the '722 application has not conceived. The first disclosure of providing or administering the LTBP-3 of the present invention to a mammal or animal occurs in the present specification on page 2 of the preliminary amendment filed June 12, 2000 (Paper No. 6) in the amendment to page 48, line 9, wherein providing or administering the LTBP-3 of the present invention to a mammal or animal is added to the present specification.

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Applicant can correct these formal matters by claiming the present application as a continuation-in-part of 08/479,722.

Since the period for reply set forth in the prior Office action has expired, this application will become abandoned unless applicant corrects the deficiency and obtains an extension of time under 37 CFR 1.136(a).

The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. In no case may an applicant reply outside the SIX (6) MONTH statutory period or obtain an extension for more than FIVE (5) MONTHS beyond the date for reply set forth in an Office action. A fully responsive reply must be timely filed to avoid abandonment of this application.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

BEFORE FINAL (703) 872-9306


AFTER FINAL (703) 872-9307

IN ADDITION TO THE OFFICIAL RIGHTFAX NUMBERS ABOVE, THE TC 1600 FAX CENTER HAS THE FOLLOWING OFFICIAL FAX NUMBERS: (703) 305-3592, (703) 308-4242 AND (703) 305-3014.

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FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

  
DAVID ROMEO  
PRIMARY EXAMINER  
ART UNIT 1647

DSR  
JUNE 3, 2003